

K160232 Disposable Barrier Sleeves and CoversJun 7, 2016
127 days to decisionK160232 · Product code: **PEM** · Dental
Source: <https://www.510kdatabase.net/k160232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dental Barriers And Sleeves (PEM)
Date received	Feb 1, 2016
Decision date	Jun 7, 2016
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply International, Inc.
Location	York, PA, US
Contact	Helen Lewis
510(k) history	36 submissions · 36 cleared · 2006-2016

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